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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/911,732	07/25/2001	Joseph Atabekov	0933-0169P	5590

2292 7590 01/10/2003

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EXAMINER

KATCHEVES, KONSTANTINA T

ART UNIT PAPER NUMBER

1636

DATE MAILED: 01/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/911,732

Applicant(s)

ATABEKOV ET AL.

Examiner

Konstantina Katcheves

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 October 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 19-39 is/are pending in the application.
- 4a) Of the above claim(s) 38 and 39 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 19-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Claims 19-39 are pending in the instant application.

Election/Restrictions

Applicant's election with traverse of Group I, claims 19-37 in Paper No. 9 is acknowledged. The traversal is on the ground that all of the claims of the invention call for the expression of a first and second structural gene. This argument is noted but not found persuasive. The invention of claims 38 and 39 are drawn to transgenic organisms. The transgenic organisms of Group II are chemically, biologically, and functionally distinct from the vector and method of Group I and thus one does not render the other obvious. The organisms of Group II inherently differ from the vector of Group I because organisms have different functions and different chemical structure than nucleic acids. Therefore, the inventions of the two groups are capable of supporting separate patents. Although Groups I and II have not been rejoined, the election of species set forth in the Restriction Requirement mailed 26 September 2003 has been withdrawn.

The requirement is still deemed proper and is therefore made FINAL. Claims 38 and 39 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 8.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 19-37 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 6, 7 and 9 of U.S. Patent No. 6,376,745 ("745 patent"). Although the conflicting claims are not identical, they are not patentably distinct from each other because the invention of the instant claims would have been obvious to one of skill in the art. The invention of the instant claims is drawn to a recombinant nucleic acid sequence comprising a transcriptional promoter, a first gene, and IRES that can promote a second gene. The invention of the prior patent disclose a recombinant nucleic acid comprising a

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promoter, a first gene, an IRES from tobamovirus and a second gene under the control of the tobamovirus IRES. The claims of the instant application and the '745 patent recite the limitation wherein the first gene is translated by a ribosome scanning mechanism and the second gene's translation is under the control of IRES from tobamovirus. The claims of the '745 patent are a species of the claims of the instant patent. Thus, the claims of the '745 patent anticipate the claims of the instant application. Therefore, the invention of the instant claims would have been obvious to one of skill in the art.

Claim Rejections - 35 USC § 112

Claims 26, 36 and 37 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for yeast cells and plant cells, does not reasonably provide enablement for other eukaryotic cells including, animal, insect, mammalian or human cells. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention without undue experimentation. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

- 1) the quantity of experimentation necessary,
- 2) the amount of direction or guidance provided,
- 3) the presence of absence of working examples,

- 4) the nature of the invention,
- 5) the state of the prior art,
- 6) the relative skill of those in the art
- 7) the predictability of the art, and
- 8) the breadth of the claims.

Although each of the factors has been considered, only those most applicable are discussed below. Therefore, upon weighing these factors, Applicant is not enabled for the full scope of the invention claimed. Applicant's invention is broadly drawn to eukaryotic cells, including yeast cells, plant cells, animal cells, insect cells, mammalian cells and human cells comprising a recombinant molecule of any one of claims 19, 20 or 21. The recombinant nucleic acid molecule of the instant claims comprises an IRES of a plant virus. Specifically, they comprise a tobamovirus.

Although recombinant technology is a fairly mature art, Applicant's specification only shows examples wherein yeast and tobacco plant cells were transformed with a nucleic acid construct comprising an IRES of a tobamovirus. Nowhere in the specification does Applicant teach the use of this construct with any other type of eukaryotic cell. Moreover, a search of the prior art failed to show instances where any plant IRES, especially a tobamovirus IRES, could be used in a polycistronic construct for the transformation of mammalian or insect cells. To emphasize the difficulty in translating success in one family of organisms to another, Urwin et al. (Plant Journal Vol.24 no.5 2000) teach that "there are no reports of animal virus derived IRES activity in plant cells." See abstract. Given the breadth of the claims and the lack of guidance or

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working examples from the specification, one of skill in the art would not be enabled for the full scope of the invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 23 and 24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 23 and 24 recite a phrase as an exemplification of IRES activity. The language in these claims set aside by the term, *i.e.*, renders the claim unclear. It is unclear whether Applicant intends the phrase immediately after *i.e.* is an actual limitation to the claims. The ambiguity of this language and terminology needs to be resolved.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 19, 20, 25, 27, 31, 34, 36 and 37 are rejected under 35 U.S.C. 102(b) as being anticipated by Thomas et al. (Journal of Virology Vol.65 no.6 1991).

Thomas et al. teach a bicistronic vector comprising a full-length clone of cowpea mosaic virus middle component RNA (CPMV M-RNA) with a T7 RNA promoter. The CPMV M-RNA

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has two functional initiation sites one at the 5' end and the other at an internal initiation site, such as an IRES of the instant claims. The two initiation sites result in the translation of two protein products, a 105 kD protein and a 95 kD protein. Thus, the Thomas et al. meet the limitations of the instant claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konstantina Katcheves whose telephone number is (703) 305-1999. The examiner can normally be reached on Monday through Friday 7:30 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel, Ph.D. can be reached on (703) 305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-7939 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-3388.

Konstantina Katcheves
January 10, 2003



**JAMES KETTER
PRIMARY EXAMINER**

DETAILED ACTION

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Election/Restrictions

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Allowable Subject Matter

Claims 28-30, 32 and 33 objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

(OBU. DOUBLE PATENTING WOULD STILL APPLY)

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konstantina Katcheves whose telephone number is (703) 305-1999. The examiner can normally be reached on Monday through Friday 7:30 to 4:30.

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Konstantina Katcheves
January 9, 2003